

SUPPORT FOR THE AMENDMENTS

Claims 1-6 were previously canceled.

Claims 7 and 9 are canceled herein.

Claims 8 and 11 have been amended.

Support for the amendment to Claims 8 and 11 is found at pages 6-7, page 8 lines 15-25, page 8, lines 32-39, page 8, lines 28-30 and page 9, lines 1-9.

No new matter has been added.

REMARKS

Claims 8, 10, and 11 are pending in the present application.

The rejection of Claims 7-10 under 35 U.S.C. §112, second paragraph, is obviated by amendment.

The Examiner objects to the phrase “cytostatic and cytotoxic effects” stating that these two effects are mutually exclusive. Applicants make no statement with respect to the propriety of this allegation and in no way acquiesce to the same. Solely to expedite examination of this application, Applicants have changed the expression “cytostatic and cytotoxic effects” to “cytostatic or cytotoxic effects”. Thus, this criticism is believed to be moot.

Withdrawal of this ground of rejection is requested.

The rejection of Claims 7 and 9 under 35 U.S.C. §102(b) over Federle et al as evidenced by Teslascan is obviated by amendment.

Applicants make no statement with respect to the propriety of this allegation and in no way acquiesce to the same. Solely to expedite examination of this application, Applicants have canceled Claims 7 and 9. Therefore, this ground of rejection is now moot.

Withdrawal of this ground of rejection is requested.

The rejection of Claims 8, 10, and 11 under 35 U.S.C. §103(a) over Federle et al in view of Towart et al as evidenced by Teslascan is obviated by amendment.

The Examiner alleges that the cited combination of references provides at least a *prima facie* case of obviousness for the claimed method for increasing the cytostatic or

cytotoxic effects on tumor cells, and decreasing the cytotoxic effect on normal leucocytes of an anticancer medicinal product where mangafodipir is administered in combination with a taxane. Applicants make no statement with respect to the propriety of this allegation and in no way acquiesce to the same. Solely to expedite examination of this application, Applicants have amended Claims 8 and 11 to limit the claims to a combination of mangafodipir and platinum derivatives. None of the cited references disclose this specific combination.

Further, the Examiner is referred to Example 3, which provides a demonstration *in vitro* of the ability of mangafodipir to increase the cytostatic and cytotoxic effects on tumor cells, and to decrease the cytotoxic effect on normal leucocytes of oxaliplatin, which is a representative of platinum derivatives. Moreover, Example 7 shows that the effects of mangafodipir *in vitro* are correlated with its effects on tumor growth *in vivo*. The experimentations described in Example 7 were performed with colon cancer cells (CT26) and liver cancer cells (Hepa 1-6 cell line). The anti-tumoral drug tested in these *in vivo* experimentations was oxaliplatin). These results show that the effects of mangafodipir *in vivo* correlate well with those which were observed *in vitro* in Example 3. The results demonstrated in Examples 3 and 7 are not disclosed, suggested, or even reasonably apparent based on the combined disclosures of Federle et al, Towart et al, and Teslascan.

Accordingly, Applicants submit that the presently claimed invention is not obvious in view of the combined disclosures of Federle et al, Towart et al, and Teslascan.

Withdrawal of this ground of rejection is requested.

Applicants submit that the present application is in condition for allowance. Early notification to this effect is respectfully requested.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



Vincent K. Shier
Registration No. 50,552

Customer Number

22850

Tel: (703) 413-3000
Fax: (703) 413-2220
(OSMMN 08/03)